

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : B.M. Cullen, et al.  
Serial No. : 10/527421 Art Unit : 3772  
Filed : November 18, 2005 Examiner : K.M. Lewis  
Title : WOUND DRESSING MATERIALS COMPRISING COMPLEXES OF  
ANIONIC POLYSACCHARIDES WITH SILVER

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04/20/2010	Julie Chan-Moroney
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<b>Signature</b>	

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Commissioner for Patents  
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**APPEAL BRIEF UNDER 37 C.F.R. §41.37**

Dear Sir:

This Appeal Brief is filed in response to the Final Rejection mailed November 20, 2009.

This Brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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1. **Real Party In Interest:**

The real party in interest for this patent application is Ethicon, Inc., U.S. Route 22, Somerville, NJ 08876.

2. **Related Appeals and Interferences:**

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. **Status of Claims:**

Claims 1, 5, 6, 10, 11, 13 and 16-18 are rejected and are the subject of the present appeal.

4. **Status of Amendments:**

No amendments have been filed after the final rejection of November 20, 2009.

5. **Summary of Claimed Subject Matter:**

The invention as presently claimed in independent Claim 1 is directed to a wound dressing material comprising a complex of an oxidized regenerated cellulose with silver, wherein the amount of silver in the wound dressing material comprises from about 0.1wt.% to about 0.3 wt% silver.

Support for Claim 1 may be found, for example, on page 1, lines 4-6 and page 4 lines 23-26 of the Specification.

The invention as presently claimed in independent Claim 13, relates to a method for treating venous ulcers, decubitus ulcers or diabetic ulcers, comprising applying a wound dressing material directly to the surface of the wound; wherein the wound dressing material comprises a

complex of oxidized regenerated cellulose with silver, wherein the amount of silver in the wound dressing material comprises from about 0.1wt. % to about 0.3 wt % silver.

Support for Claim 13 may be found, for example, on page 10, lines 8-13 and page 4 lines 23-26 of the Specification.

6. **Grounds of Rejection to be Reviewed on Appeal:**

6.1 Whether Claims 1, 5, 6, 10, 11, 13 and 16-18 are unpatentable under 35 U.S.C. 103 (a) as obvious over GB 2,314,842 (Watt) in view of US 6,409,881 (Jaschinski).

6.2 Whether Claim 11 is unpatentable under 35 U.S.C. 103 (a) as obvious over GB 2,314,842 (Watt) in view of US 6,409,881 (Jaschinski) as applied to Claim 11 above and further in view of US 3,032,182 (Bachtold).

7. **Argument:**

7.1 Claims 1, 5, 6, 10, 11, 13 and 16-18 are patentable under 35 U.S.C. 103 (a) and not obvious over GB 2,314,842 (Watt) in view of US 6,409,881 (Jaschinski).

By way of review the present invention is directed to the use of a specified low concentration range of silver from 0.1 wt.% to 0.3 wt.% in order to achieve both an antimicrobial effect and a surprising proliferative effect on wound healing cells. The range of 0.1 wt.% to 0.3wt.% silver is substantially lower than the conventional range for antimicrobial silver-containing wound dressings. However, the present inventors have found that such a low silver concentration range is needed in order to achieve the proliferative effect on wound healing cells. Even at slightly higher silver contents, e.g. 0.5 wt% (as disclosed by Jaschinski, see below), the silver has been demonstrated to have an antiproliferative effect on wound healing cells.

For support of the technical effects underlying the present invention, the Appellant refers to the examples of the present application. The inventors have indicated that the actual

silver content in of the materials in the wound dressings studied in the examples was as follows:

Reference example 2	11.25 wt.% Ag
Reference example 3	5 wt.% Ag
Reference example 4	2.5 wt.% Ag
Reference example 5	0.5 wt.% Ag
Example 6	0.25 wt.% Ag
Reference example 7	0.05 wt.% Ag

The data presented in the present application show that the antimicrobial effect of the silver is lost at the low silver concentration of reference example 7 (i.e., at 0.05 wt.% Ag) , and that the proliferative effect of the silver is lost at the relatively higher silver concentrations of reference examples 2-5 (i.e., at 0.5 wt.% Ag and higher).

The proliferative effect of silver at the low concentration range from 0.1 to 0.3 weight % is a completely new discovery, supported by the above cited data. Furthermore, it has also been discovered that the same low concentrations of silver has anti-inflammatory potential.

The Examiner finally rejected claims 1,5,6,10,13, and 16-18 under 35 USC 103(a) as being unpatentable over GB 2,314,842 (Watt) in view of US 6,409,881 (Jaschinski).

The Examiner cites Watt for disclosing oxidized regenerated cellulose and collagen complexes and acknowledges the lack of disclosure in Watt for silver containing compositions and then cites Jaschinski for disclosing treatment of “oxidized cellulose with a silver based antibacterial agent in an amount of 0.1 wt% to 25 wt. % (particularly 0.1 wt% to 0.5 wt%) (col. 24, lines 37-51) in order to confer antibacterial properties to medical products for the inherent purpose of preventing bacterial growth.” The Examiner then concludes that claimed ranges that “overlap or lie inside ranges disclosed by the prior art” is prima facie obvious.

Firstly, Applicants submit that the Examiner has failed to provide a prima facie obviousness rejection as there is no suggestion nor disclosure **that an oxidized regenerated cellulose-silver complex first be formed** and then incorporated as part of a wound dressing. Instead the Examiner’s combination of references is at best directed toward treating complexes

of oxidized regenerated cellulose (ORC) - collagen (as disclosed by Watt) with silver (as disclosed by Jaschinski). Again the Examiner's combination does not suggest nor teach why one skilled in the art should first complex the oxidized regenerated cellulose with silver in forming a wound dressing so that the overall wound dressing's silver content (contributed by the ORC-silver complex) is in the range of 0.1 wt % to 0.3 wt. %.

Secondly, there is no suggestion in the cited documents that maintaining the silver content from the ORC-silver complex in the in the range of 0.1 wt % to 0.3 wt % would achieve the proliferative and anti-inflammatory effects identified by the present inventors. There is no teaching or suggestion in any of the cited documents that this object can be achieved by complexing oxidized regenerated cellulose with silver and then maintaining or reducing the silver content to the range of 0.1 to 0.3 wt. % in the final wound dressing material. Referring back to the data cited above, the data presented in the present application show that the antimicrobial effect of the silver is lost at the low silver concentration of reference example 7 (i.e., 0.05 wt.% Ag), and that the proliferative effect of the silver is lost at the relatively higher silver concentrations of reference examples 2-5 (i.e., at 0.5 wt.% Ag and higher). Thus, even the preferred range of Jaschinski of 0.1 to 0.5 wt. % silver would yield compositions in which the proliferative effect of silver is lost.

The proliferative effect of silver at the low concentration range from 0.1 to 0.3 weight % is a completely new discovery, supported by the above cited data. Furthermore, it has also been discovered that the same low concentrations of silver has anti-inflammatory potential.

Appellant respectfully requests reversal of this rejection.

7.2 Claim 11 is patentable under 35 U.S.C. 103 (a) as not obvious over GB 2,314,842 (Watt) in view of US 6,409,881 (Jaschinski) as applied to Claim 11 above and further in view of US 3,032,182 (Bachtold).

The Examiner rejected claim 11 under 35 USC 103(a) as being unpatentable over Watt in view of Jaschinski and further in view of US 3,032,182 (Bachtold). The Examiner cites

Bachtold further in view of the rejection of Watt in view of Jaschinski for Bachtold's disclosure of sterile packaging.

The Appellant incorporates the arguments provided above as applied to claims 1,5,6,10,13, and 16-18 in view of Watt and Jaschinski. The Examiner's citing of Bachtold adds nothing further in view of the Examiner's rejection of Watt and Jaschinski to correct the deficiencies previously identified by Appellant. Therefore, the rejection further in view of Bachtold is respectfully requested to be reversed.

7.3 **Conclusion:**

For the reasons discussed above, Appellant maintains that the Examiner's final rejection of claims 1, 5, 6, 10, 11, 13 and 16-18 as being unpatentably obvious should be reversed.

Respectfully submitted,

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## **8. CLAIMS APPENDIX**

Claim 1. (Appealed) A wound dressing material comprising a complex of an oxidized regenerated cellulose with silver, wherein the the amount of silver in the wound dressing material comprises from about 0.1wt.% to about 0.3 wt% silver .

Claim 2. (Cancelled)

Claim 3. (Cancelled)

Claim 4. (Cancelled)

Claim 5. (Appealed) A wound dressing material according to claim 1, wherein the amount of silver in the complex is from about 1 to about 50% by weight based on the weight of the oxidized cellulose.

Claim 6. (Appealed) A wound dressing material according to claim 1, in the form of a freeze-dried sponge sheet, or a woven or nonwoven fibrous sheet, or a gel sheet.

Claim 7. (Cancelled)

Claim 8. (Cancelled)

Claim 9. (Cancelled)

Claim 10. (Appealed) A wound dressing comprising a wound dressing material according to claim 1.

Claim 11. (Appealed) A wound dressing according to claim 10, wherein the wound dressing is sterile and packaged in a microorganism-impermeable container.

Claim 12. (Cancelled)

Claim 13. (Appealed) A method for treating venous ulcers, decubitis ulcers or diabetic ulcers, comprising applying a wound dressing material directly to the surface of the wound; wherein the



wound dressing material comprises a complex of oxidized regenerated cellulose with silver, wherein the amount of silver in the wound dressing material comprises from about 0.1 wt. % to about 0.3 wt % silver.

Claim 14. (Cancelled)

Claim 15. (Cancelled)

Claim 16. (Appealed) The wound dressing material of claim 1, wherein the material further comprises collagen.

Claim 17. (Appealed) The wound dressing material of claim 16, wherein the material comprises a mixture of collagen and oxidized regenerated cellulose in the weight ratio of 60:40 to 40:60.

Claim 18. (Appealed) the wound dressing material of claim 17, wherein the material is a freeze-dried sponge.

**9. EVIDENCE APPENDIX**

None

**10. RELATED PROCEEDINGS APPENDIX**

None